

AMENDED IN ASSEMBLY MARCH 18, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 2605

Introduced by Assembly Member Bonilla

February 21, 2014

An act to amend Section ~~4127.2~~ 4200.3 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2605, as amended, Bonilla. Pharmacy: sterile drug products.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. ~~Existing law, until July 1, 2014, prohibits a nonresident pharmacy from compounding injectable sterile drug products for shipment into the state without a license issued by the board, and specifies the information the board is required to receive before issuing the license. Existing law, commencing July 1, 2014, expands that provision to apply to nonresident pharmacies that compound any sterile drug products, and specifies different information the board is required to receive before issuing the license. Existing law requires an applicant for licensure to have, among other things, passed specified national and state examinations. Existing law requires the examination process to be regularly reviewed, as specified, and to meet certain national testing standards. Existing law requires the board to report to the Joint Committee on Boards, Commissions, and Consumer Protection and the Department of Consumer Affairs, as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination, as specified.~~

~~This bill would, with regard to the provisions that become inoperative July 1, 2014, prohibit the board from issuing a license to a nonresident pharmacy until the board receives any other information the board deems necessary. This bill would instead require the board to report the pass rate information described above to the appropriate policy committees of the Legislature and the department.~~

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4200.3 of the Business and Professions
- 2 Code is amended to read:
- 3 4200.3. (a) The examination process shall be regularly
- 4 reviewed pursuant to Section 139.
- 5 (b) The examination process shall meet the standards and
- 6 guidelines set forth in the Standards for Educational and
- 7 Psychological Testing and the Federal Uniform Guidelines for
- 8 Employee Selection Procedures. The board shall work with the
- 9 Office of Professional Examination Services of the department or
- 10 with an equivalent organization who shall certify at minimum once
- 11 every five years that the examination process meets these national
- 12 testing standards. If the department determines that the examination
- 13 process fails to meet these standards, the board shall terminate its
- 14 use of the North American Pharmacy Licensure Examination and
- 15 shall use only the written and practical examination developed by
- 16 the board.
- 17 (c) The examination shall meet the mandates of subdivision (a)
- 18 of Section 12944 of the Government Code.
- 19 (d) The board shall work with the Office of Professional
- 20 Examination Services or with an equivalent organization to develop
- 21 the state jurisprudence examination to ensure that applicants for
- 22 licensure are evaluated on their knowledge of applicable state laws
- 23 and regulations.
- 24 (e) The board shall annually publish the pass and fail rates for
- 25 the pharmacist's licensure examination administered pursuant to
- 26 Section 4200, including a comparison of historical pass and fail
- 27 rates before utilization of the North American Pharmacist Licensure
- 28 Examination.

(f) The board shall report to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* and the ~~department~~ *department*, as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SECTION 1. Section 4127.2 of the Business and Professions Code is amended to read:

4127.2. (a) ~~A nonresident pharmacy shall not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.~~

(b) ~~A license to compound injectable sterile drug products shall be issued only for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products shall be issued only to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products shall not be issued or renewed until the board receives the following from the nonresident pharmacy:~~

(1) ~~A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.~~

(2) ~~A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.~~

(3) ~~Any other documentation the board deems necessary.~~

(c) ~~Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.~~

(d) ~~On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the~~

1 manner required pursuant to Section 9795 of the Government
2 Code. At a minimum, the report shall address all of the following:

3 (1) ~~A detailed description of board activities related to the~~
4 ~~inspection and licensure of nonresident pharmacies.~~

5 (2) ~~The status of proposed changes to federal law that are under~~
6 ~~serious consideration and that would govern compounding~~
7 ~~pharmacies, including legislation pending before the United States~~
8 ~~Congress, administrative rules, regulations, or orders under~~
9 ~~consideration by the federal Food and Drug Administration or~~
10 ~~other appropriate federal agency, and cases pending before the~~
11 ~~courts.~~

12 (3) ~~If applicable, recommended modifications to the board's~~
13 ~~statutory duties related to nonresident pharmacies as a result of~~
14 ~~changes to federal law or any additional modifications necessary~~
15 ~~to protect the health and safety of the public.~~

16 (e) ~~This section shall become inoperative on July 1, 2014, and,~~
17 ~~as of January 1, 2015, is repealed, unless a later enacted statute,~~
18 ~~that becomes operative on or before January 1, 2015, deletes or~~
19 ~~extends the dates on which it becomes inoperative and is repealed.~~